

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO**

DARRYL DURR,

Plaintiff,

Case No. 2:10cv288

v.

District Judge Gregory Frost

TED STRICKLAND, Governor, et al.

Defendants.

**DEFENDANTS' MEMORANDUM IN REPLY TO DURR'S MEMORANDUM IN
OPPOSITION TO DEFENDANTS' MOTION TO DISMISS**

Next Tuesday, Darryl Durr is scheduled to be executed by the State of Ohio for the murder of Angel Vincent. *State v. Durr*, 58 Ohio St. 3d 86 (1991). Currently, the Warden is under an Order issued by the Ohio Supreme Court to execute Durr.¹ *See also*, OHIO REV. CODE § 2949.24. In the present suit, Durr has sought a declaratory judgment to determine whether Ohio's lethal injection protocol violates either the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, *et. seq.* or the Controlled Substances Act, 21 U.S.C. §§ 801, *et. seq.* Durr is not requesting injunctive relief. Defendants have brought a motion to dismiss based on Durr's lack of standing and lack of a private right of action. At this juncture, the merits of the case are not before this Court.

1. Durr lacks standing.

To have standing, Durr must allege and prove that he has suffered injury which is traceable to Defendant's allegedly unlawful conduct and will likely be redressed by the

¹ <http://www.sconet.state.oh.us/tempx/179513.pdf>.

requested relief. *Allen v. Wright*, 468 U.S. 737, 751 (1984). Durr has not alleged any specific injury to him as a result of defendants' alleged failure to comply with the law. He has not even alleged that any act by defendant has injured or will injure him. And, even if his general averment that defendants will violate the law is considered an averment of "injury," Durr still lacks standing because this alleged "injury" does not fall within the zone of interests protected or regulated by either the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, *et. seq.* or the Controlled Substances Act, 21 U.S.C. §§ 801, *et. seq.*. 'The phrase 'person adversely affected or aggrieved' is a term of art used in many statutes to designate those who have standing to challenge or appeal an agency decision, within the agency or before the courts.'" *Dir., Office of Workers' Comp. Programs v. Newport News Shipbuilding & Dry Dock Co.*, 514 U.S. 122, 126 (1995). Neither FDCA nor CSA were intended to benefit death row inmates who seek to challenge the lethal injection protocols of the States.

2. Neither the FDCA, nor the CSA, create a cause of action.

The Court shall not recognize a private right of action unless it determines that Congress intended to create a cause of action. *Touche Ross & Co. v. Redington*, 442 U.S. 560 (1979); *Alexander v. Sandoval*, 532 U.S. 275, 286-87 (2001). Congress never intended private right of action under the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, *et. seq.* See, *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995); *Mylan Labs. Inc. v. Matkar*, 7 F.3d 1130, 1139 (4th Cir. 1993). *In re Orthopedic Bone Screw Prods. Liab. Lit.*, 193 F.3d 781, 788-789 (3rd Cir. 1999); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3rd Cir. 1994). If Congressional intent is not present, courts must conclude that "the essential predicate for implication of a private remedy" do not exist. *Thompson*

v. Thompson, 484 U.S. 174, 179 (1988). Furthermore, this Court must determine whether “in drafting (legislation)... Congress intended for prospective plaintiffs to have a private cause of action to seek declaratory or injunctive relief for an alleged systemic violation.” *Jackie S. v. Connelly*, 442 F. Supp. 2d 503, 525 (S.D. Ohio 2006).

The primary purpose of the FDCA is to protect the public by preventing untested, misbranded, and dangerous items and products from entering interstate commerce. 21 U.S.C. § 321. To accomplish this goal, 21 U.S.C. § 332(a) states “the district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, to restrain violations of this Act.” However, § 337(a) provides that “all such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States.” 21 U.S.C. § 337(a). In *Bailey*, the Sixth Circuit specifically found that Congress had even rejected several attempts by individual legislators to place a private cause of action in the statute originally. 48 F.3d at 967-968. Clearly, Congress never intended for private parties, much less death row inmates, to seek injunctive relief under the statute. In fact, this explains why inmates previously sought to force the United States Government’s hand in *Heckler v. Chaney*, 470 U.S. 821 (1985) as opposed to just bringing a private cause of action themselves.

Durr’s reliance on *Ben Venue Laboratories v. Novartis Pharmaceutical Corp.*, 10 F. Supp.2d 446 (D.N.J. 1998) is misplaced. In *Ben Venue*, the plaintiff, an alleged patent infringer, brought a declaratory judgment action claiming that defendant’s patents, through deceit, were improperly listed in the Orange Book. The court held that 21 U.S.C. 355(j)(5)(B)(iii)(III) “is limited to declaratory judgment actions ... aimed solely at the narrow patent issues of infringement and invalidity.” *Id.* at 451. *Ben Venue* allows for a

declaratory judgment action is such circumstances because the issues implicated deal almost exclusively with patent law, which is beyond the FDA's expertise. *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1379 (D.C. Cir. 2002). In *Ben Venue*, the court expressly found that "[t]he limited legislative history also suggests that Congress enacted this provision specifically with invalidity or infringement suits in mind." *Id.* at 451. Durr's complaint has nothing to do with patent law.

Furthermore, the Controlled Substances Act, 21 U.S.C. §§ 801, *et. seq.*, contains no language that even resembles a private right of action. *McCallister v. Purdue Pharma L.P.*, 164 F. Supp. 2d 783, 793 (S.D. W.Va., 2001). Section 877 only allows for judicial review of determinations made by the Attorney General regarding controlled substances. 21 U.S.C. § 877. The CSA does not confer any rights at all upon Durr or any other death row inmate. *Gonzaga Univ. v. Doe*, 536 U.S. 273 (2002). In *Gonzaga Univ.*, the Supreme Court held that when determining whether Congress intended a cause of action, courts must "determine whether or not a statute confers rights on a particular class of persons." *Id.* at 284-85. *See also, Bonds v. Tandy*, 457 F.3d 409 (5th Cir. 2006). In light of the statutes language, structure, and legislative history, it is clear that a private right of action was specifically precluded.

CONCLUSION

WHEREFORE, for all the foregoing reasons, Defendant respectfully moves the Court to dismiss Durr's Complaint, because it fails to state a claim for which relief may be entitled and the Court lacks jurisdiction

Respectfully submitted,

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/s/ Charles L. Wille

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of DEFENDANTS' MEMORANDUM IN REPLY was filed electronically this 14th day of April 2010. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/ *Charles L. Wille*

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